The influence of obesity and age on outcomes of Minimally Invasive Lumbar Fusion (MILIF): A subgroup analysis of a 1 year prospective multicenter observational study

Wolfgang Senker1, Ulrich Hubbe2, Paulo Pereira3, Khai Lam4, Salvador Fuster5, Neil Manson6
1 Landesklinikum Mostviertel Amstetten, Austria, 2 Universitätsklinikum Freiburg, Germany, 3 Centro Hospitalar S. Joao, Portugal 4 Guy's and St Thomas' NHS Hospitals London, UK, 5 Hospital Clínic de Barcelona IBT (Institut Barceloní de Traumatologia) Clínica Corachán, Spain, 6 Canada East Spine Centre and Horizon Health Network, Canada

EUROSpine 2015
COPENHAGEN, DENMARK
MASTERS-D Study Design and Objective

Multi-center, Prospective, Post-market, Observational
NCT01143324

Indication:
Single or double level MIS fusion procedure with CD Horizon® Spinal System using PLIF or TLIF for treatment of degenerative lumbar spine

255 pts from 19 sites / 14 countries

Med Hx
Pain Meds
Demographics
Work status (WS) EQ-D QoL

Surgery

VAS, Pain Meds, AEs
QoL, Pain Meds, AEs, Rehab, WS, Pt Satisf.
QoL, Pain Meds
AEs, Rehab,
WS, Pt Satisf, Imaging

FPI: 24 Jun 2010
LPI: 24 Aug 2011

Primary Endpoint:
Short term recovery after surgery (Time to 1st ambulation and Surgery Recovery Day=potential release)

Secondary endpoints:
Clinical and radiological outcomes one year after surgery.

252 pts
249 pts
244 pts
241 pts
233 pts

doi:10.1371/journal.pone.0122312
http://127.0.0.1:8081/plosone/article?id=info:doi/10.1371/journal.pone.0122312
### Patient demographics primary population

#### Baseline Characteristics

<table>
<thead>
<tr>
<th>Metric</th>
<th>N patients = 252</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Females)</td>
<td>56.3%</td>
<td></td>
</tr>
<tr>
<td>Mean Age in years</td>
<td>53.8 (11.8)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>27.7 (4.6)</td>
<td></td>
</tr>
<tr>
<td>Duration of symptoms resulting in surgery in months</td>
<td>28.5 (38.2)</td>
<td></td>
</tr>
<tr>
<td>Duration of conservative treatment in months</td>
<td>20.7 (34.3)</td>
<td></td>
</tr>
<tr>
<td>Pre-existing conditions relevant to study</td>
<td>37.3%</td>
<td></td>
</tr>
<tr>
<td>Previous lumbar surgeries</td>
<td>18.7%</td>
<td></td>
</tr>
<tr>
<td>- At target level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Microdiscectomy Open Surgery</td>
<td>15.1%</td>
<td></td>
</tr>
<tr>
<td>- Microdiscectomy Minimal Invasive Surg.</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>- Decompression</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.6%</td>
<td></td>
</tr>
</tbody>
</table>

#### Main pathologies

<table>
<thead>
<tr>
<th>Pathology</th>
<th>N</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spondylolisthesis</td>
<td>133</td>
<td>52.8%</td>
</tr>
<tr>
<td>Stenosis</td>
<td>180</td>
<td>71.4%</td>
</tr>
<tr>
<td>Disc Pathology</td>
<td>236</td>
<td>93.7%</td>
</tr>
<tr>
<td>Other</td>
<td>21</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

---

Objectives

Investigate whether outcomes of MILIF for degenerative lumbar disorders (DLD) are affected by age or weight using data from the MASTERS-D trial (NCT01143324).

The following endpoints were evaluated:
1. Primary endpoints:
   • Time to surgery recovery
   • Time to ambulation

2. Secondary endpoints:
   • ODI
   • VAS leg pain
   • VAS back pain
Patients subgroups

Number of patients per age group

- <=50
- 51-64
- >=65

Number of patients per weight class

- Normal (min - 25.0)
- Overweight (25.1 - 29.9)
- Obese (30.0 - max)
Effect of age on first ambulation (TFA) and time to surgery recovery (TPSR)

Kruskal Wallis Age p=0.8707

There was a linear relationship between TPSR and age, p=0.0028
Effect of weight on first ambulation (TFA) and time to surgery recovery (TPSR)

There was a linear relationship between TPSR and BMI, $p=0.0024$

Kruskal Wallis BMI $p=0.1013$

BMI $p=0.1591$
ODI improved regardless of age or weight

Baseline to 12m: \( p<0.0001 \)

Heavier patients started off with worse ODI, \( p=0.0394^* \)
VAS Leg pain improved

Baseline to 12m: p<0.0001
VAS Back pain improved

Baseline to 12m: p<0.0001
EQ-5D improved

Baseline to 12m: p<0.0001
Low number of MILIF related AEs

### Age

<table>
<thead>
<tr>
<th>Lowest level term</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22 (4)</td>
<td>1</td>
<td>14 (1)</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

| AE rates (%)       | 0.98 | 21.57 | 0.98 | 13.72 | 2.08 | 29.17 |

### Weight

<table>
<thead>
<tr>
<th>Lowest level term</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
<th>MAST</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
<td>2 (1)</td>
<td>22 (5)</td>
<td>0</td>
<td>17 (4)</td>
<td></td>
</tr>
</tbody>
</table>

| AE rates (%)       | 1.26 | 13.92 | 1.92 | 21.15 | 0    | 24.63 |
General Conclusions

- MILIF and BMI and Age
  - All PROs improved regardless of weight or age
  - Low morbidity
  - All patients recover between 2-3 days
  - Older and heavier patients need an additional 24 h to recover
Acknowledgements

- **MASTERS-D study investigators**
  Drs Pereira, Hubbe, Manson, Franke, Buzek, Kosmala, Rosenberg, Assietti, Martens, Lam, Barbanti, Durny, Lidar, Richter, Sloniewski, Fuster, Vougioukas, Schroder

- **All patients who participated in the study, staff who contributed to the conduct of the study and Medtronic Spinal & Biologics**
Conflict of Interest Disclosure related to this work

All authors participated of the MASTERS-D clinical trial which was sponsored by Medtronic

W. Senker: Consultant Medtronic
U. Hubbe: Consultant Medtronic
P. Pereira: Consultant Medtronic
K. Lam: No other conflict of interest
K. Fuster: No other conflict of interest
N. Manson: Consultant Medtronic